EPA's Scope Documents for First 10 Chemicals to Undergo Risk Evaluation Under TSCA

EPA Response to Interagency Comments Received as of cob on 6/15/2017

DRAFT as of June 15, 2017; 9:28pm

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General Comments

General Comment from HHS: EPA has undertaken a huge task to get the ten scoping documents published within statutory deadlines and before finalization of the risk evaluation process. NIOSH understands that because of this there is only very limited time for review. Therefore, the review undertaken was necessarily hasty and does not constitute a thorough review.

NIOSH also understands that because of the deadlines, the scoping documents are not as refined as EPA would prefer and therefore EPA intends to publish "Problem Formulation" documents for these 10 chemicals within approximately six months in order to give the public, federal agencies, and other stakeholders additional information on the scoping and opportunity to provide more substantive comments. NIOSH looks forward to reviewing more refined scoping documents.

Overall, the general format to the scoping documents is very useful. The documents clearly outline the data collection sources and methods, the conceptual models of exposure, and the exposures and health effects that will be considered in the risk assessments. However, the scoping documents include a great deal of boilerplate material and less actual specifics than would be desired in a risk evaluation plan. That being said, certain of the documents (1-BP, methylene chloride and trichloroethylene, for example) do contain a good deal of chemical-specific information and a more fleshed-out initial analysis plan, but these are also the chemicals for which some risk assessments have been completed under the TSCA Workgroup Plan.

One caution in evaluating occupational exposure measurements, EPA should be sure that the time-weighted average values they are reporting reflect what an actual worker might be exposed to. Compliance samples are frequently collected to look for the worst case scenarios and may include task-based sampling that measures exposures during a specific task. Extrapolating these exposures to an 8-hour time-weighted average may be inappropriate if the task is only conducted for a few minutes during a worker's day. Whenever possible, EPA should look to occupational exposure sampling designed to fully characterize worker exposure.

EPA is to be commended for pulling these documents together in such a short amount of time. They represent a substantial staff effort and thoughtful planning. In particular, the uses and exposure information that EPA has collected to guide the risk evaluation plan is of use to both risk assessors and stakeholders as it provides a synopsis of EPA's understanding of where potentially problematic exposures may be occurring in workplaces, homes and the environment.

EPA Response:

General Comments from DOL/OSHA: DOL reviewed four of the ten scoping documents for TSCA risk evaluation under TSCA; these are the documents for which DOL provided exposure data to EPA. Those four documents were for 1-bromopropane (1BP), dichloromethane (DCM), trichloroethylene (TCE), and perchloroethylene (PERC), and also commented on Asbestos. Comments related specifically to each of these Scope documents are listed in the chemical section below and the following comments are universal among all 10 of the draft documents

(1) In section 2.2.2, the statement "For risk evaluations, EPA will assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory." OSHA suggests more clarification. For the chemicals reviewed, there are often over 50 subcategories for a single chemical. Will unreasonable risk determinations be evaluated for each subcategory? Is there a process to eliminate certain subcategories or to group subcategories? Such a process might make the assessment process more manageable.

EPA Response:

(2) Consider that when these chemicals are created as intermediates that some processes might be contained and the chemical entirely consumed. In these instances, there would likely be no observable occupation exposure.

EPA Response:

(3) Sampling data in Table 2-7 may be inaccurate. Some reported 8 hr TWAs may be misreported. OSHA provided a corrected data set for 1BP and is open to work with EPA to revise the data for the other chemicals.

EPA Response:

(4) Section 2.6.1.4 bullet 6, what does EPA mean by a weight of evidence approach? Can you cite another document or explain in detail what is meant?

EPA Response:

(5) Section 2.6.3 Risk Characterization lacks key details on EPA's approach. Will this be done in line with previous TSCA risk characterizations? How will exposure be characterized?

EPA Response:

Asbestos

Comment #1: HHS noted that EPA has adopted the definition of asbestos as defined by TSCA Title II (1986) as the "asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite, or actinolite. They reiterate the IARC definition as "a generic commercial designation for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series." There is no mention of naturally-occurring cleavage fragments.

EPA has determined that the only asbestos used in this country is imported and the only form of asbestos imported is chrysotile, all used in the chlor-alkali industry, although there are some asbestos-containing products also imported. Legacy uses of asbestos are excluded from the scope of the risk evaluation. This includes pre-existing materials currently in place within buildings and equipment. These uses are enumerated in the scoping document.

Page 33, Table 2-6: Units for 8-hour TWA concentration are incorrect. "(ppm)" should be "(f/cc)".

EPA Response:

Comment #2: Page 35-36, Section 2.3.5.4. HHS noted that in the discussion of susceptible subpopulations (top of page 36), EPA mentions fire fighters coming in contact with building materials. This conflicts with the exclusion of legacy uses of asbestos in building materials. EPA should clarify its intent here. NIOSH supports evaluation of the risks to fire fighters, but understands EPA's desire to exclude legacy uses of substances. In this case, perhaps EPA should make an exception to the legacy exclusion because of the extreme persistence of asbestos in the human environment. This is especially important for fire fighters or building demolition, since the legacy asbestos would pose a "new" hazardous exposure to those workers.

EPA Response:

Comment #3: HHS indicated that additional occupational exposure data may be found in NIOSH Health Hazard Evaluations. A preliminary search of the database found 263 HHEs that may have some exposure information on asbestos.

EPA Response:

Comment #4: Page 13, End of first full paragraph, DOL highlighted this text: "During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks." Corresponding DOL comment: *What agency determines whether the condition of use has been "adequately addressed" or whether a risk has been "effectively managed"? Does simply having a standard addressing the hazardous substance mean that the condition of use is adequately addressed? If so, what happens when OSHA seeks to amend a health standard (for example, by raising the PEL)? Can it be said that the risk is still "effectively managed" by the OSHA standard?*

EPA Response:

Comment #5: Page 31, Section 2.3.5.1., Second paragraph. DOL suggests this change: "EPA considers inhalation ~~to~~ of asbestos fibers to be the most likely asbestos exposure pathway for workers and occupational non-users."

EPA Response:

Comment #6: Page 32, Last bullet at top of page. DOL highlighted part of the bullet: "Handling, transporting and disposing waste containing asbestos." Corresponding DOL comment: *It is unclear to*

me whether EPA intends to include asbestos abatement and removal? The language on page 9 suggests that some disposals of asbestos are excluded from the scope of the risk evaluation: "asbestos-containing materials that remain in older buildings or are part of older products but are no longer manufactured (including imported), processed, or distributed in commerce for that use."

EPA Response:

Comment #7: Page 35, Section 2.3.5.4., first sentence, second paragraph. DOL suggests removing the comma between "*greater exposure*" and "that."

EPA Response:

Comment #8: Page 36, top of page. DOL highlighted this sentence: "The population most likely to have high exposure to asbestos are workers who come into contact with asbestos while on the job {ATSDR, 2001, 3098571}." Corresponding DOL comment: *This supports including asbestos abatement/removal, even in older buildings.*

EPA Response:

Bromopropane

Comment #1: Appendix A-1; P. 54., DOE asked that the following be inserted at the end of the table:

Department of Energy	The Atomic Energy Act authorizes DOE to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for 1-BP is 10 ppm (8hr Time Weighted Average).

EPA Response: OK.

Comment #2: HHS commented that, since the EPA has completed a draft risk assessment for 1-BP (2016), this scoping document is fairly well fleshed out and focuses on the greatest and most hazardous exposures. It provides a reasonably thorough description of the uses of 1-BP to be considered, the populations at risk, and the health endpoints to be considered. Although the scope is broad and details of the analysis plan are sparse, it provides a good foundation for the risk assessment and alerts the public to the data available to the EPA and currently under evaluation. NIOSH is particularly interested in how EPA will be utilizing recent genotoxicity data to inform its risk assessment.

EPA Response:

Comment #3: Page 30, 1st paragraph, last sentence: HHS asked if the reference should be to the NTP monograph on 1-BP, as NTP is the entity that has classified 1-BP as "reasonably anticipated to be a human carcinogen" (although it was also reported in the ATSDR Tox Profile, that is not the primary reference).

EPA Response:

Comment #4: Page 21, first full paragraph, DOL/OSHA highlighted this text: "Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR and included in the life cycle diagram are summarized below." Corresponding DOL/OSHA comment: *What about coatings? The Department of Defense (DoD), in its 2013 Risk Alert, noted 1-bromopropane as an ingredient in coatings. Also, the California Department of Public Health, in its Dec 2016 Health Hazard Alert, noted that workers are exposed to 1-bromopropane when applying coatings to pipes or other fixtures. EPA SNAP, in its 2007 Notice of Proposed Rulemaking, noted a petition to allow the use of 1-bromopropane instead of methyl chloroform for ammunition coating (72 FR 103 at 30173, 30179).*

EPA Response:

Comment #5: Page 30, last full paragraph, DOL/OSHA highlighted the following text: "Data that inform occupational exposure assessment and which EPA expects to consider is the OSHA Chemical Exposure Health Data (CEHD), (1) which are monitoring data collected during OSHA inspections. A preliminary summary of these data is presented in **Error! Reference source not found.**. These data represent actual exposure levels at 1-BP specific workplaces encompassing several industry sectors and conditions of use. As the table shows, workers may be exposed to 1-BP at levels above 100 ppm 8-hour time-weighted average (TWA) under certain conditions of use. (2)" Corresponding DOL/OSHA comments: (1) *We provided data from OSHA Information System IOIS). (2) Some of the data points*

provided in the OIS report were not 8-hr TWA concentrations. In some cases, they were TWA concentrations for the total time sampled, which was often less than 8 hours. We have added the actual sampling times and results to the OIS data spreadsheet, and calculated 8-hr TWA concentrations assuming an exposure of 0 for the unsampled times of the 8-hr shift. This has resulted in several changes to your table. Please let us know if you have any questions.

Table 2-5. Summary of Personal Monitoring Air Samples Obtained from OSHA Inspections for 1-BP (2013 to 2016)

(1)

NAICS	NAICS Description	8-Hour TWA Concentration (ppm)*				
		Number of Data Points	Minimum	Maximum	Average	Number of Zero Values
336412	Aircraft engine and engine parts manufacturing	~~41~~	~~1.4~~	~~3.6~~	~~2.5~~3.6	0 (2)
448190	Other clothing stores	~~63~~	0.2	0.6	0.4	0
333517	Machine tool manufacturing	2	~~8.6~~0.4	~~11.0~~3.9	~~9.8~~2.2	0
334418	Printed circuit assembly	~~64~~	~~10.2~~2.2	~~290.0~~10.2	~~119.9~~6.0	0
331210	Iron and steel pipe and tube manufacturing from purchased steel	6	~~4.7~~0.2	80.~~0~~4	29.~~7~~1	0
336413	Other aircraft parts and auxiliary equipment manufacturing	~~53~~	~~2.3~~1.6	~~52.0~~12.5	~~24.4~~5.8	0
332813	Electroplating, plating, polishing, anodizing and coloring	~~21~~	~~31.2~~	~~46.0~~	~~38.6~~31.2	0
926150	Regulation, licensing and inspection of miscellaneous commercial sectors	42	0.4	24.1	12.3	0 (3)
323113	Commercial screen printing	~~21~~	~~0.0~~	~~14.0~~	~~7.0~~5.7	~~1~~0
332913	Plumbing fixture fitting and trim manufacturing	1	~~13.0~~	~~13.0~~	~~13.0~~11.1	0
332721	Precision turned product manufacturing	7	0.0	~~25.0~~3.2	~~8.1~~1.3	1
333911	Pump and pumping equipment manufacturing	~~21~~	~~1.5~~	~~2.0~~	~~1.8~~1.5	0

* For total sampling times less than 8 hours, zero exposure was assumed ~~Assumes all TWA data are 8-hour TWA.~~ for the unsampled time of the 8-hr shift.

DOL/OSHA Comments on Table:

(1) *Revised footnote. In calculating 8-hr TWA concentrations, OSHA assumes an exposure of 0 for the unsampled times of the shift.*

(2) *Only 1 worker was sampled here. See the Exposure Record column in the spreadsheet.*

(3) *This is the NAICS code for OSHA inspection staff, and it doesn't seem to be used consistently in the data set. Suggest deleting.*

EPA Response:

Comment #6: Page 44, Section 2.6.1.4. Occupational Exposures, item #6. DOL/OSHA highlighted the following text: "6) Evaluate the weight of evidence of occupational exposure data." Corresponding DOL/OSHA comments: *Might describe a bit more here.*

EPA Response:

Comment #7:

Carbon Tetrachloride (Methane, tetrachloro-)

Comment #1: Appendix A-1; P. 58., DOE asked that the following be inserted at the end of the table:

Department of Energy	The Atomic Energy Act authorizes DOE to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for carbon tetrachloride is 5 ppm (8hr Time Weighted Average) and 10 ppm Short Term Exposure Limit (STEL).

EPA Response: OK.

Comment #2: HHS noted that this scoping document represents EPA's first assessment of the risks of carbon tetrachloride exposure under new TSCA. They note that carbon tetrachloride has been eliminated from most uses and banned in consumer products. However, it is still used, primarily as feedstock in the production of other chemicals, but EPA has also identified some other uses that may exist in solvent cleaning, adhesives, paints, coatings, rubber, cement, and asphalt formulations. Some products may contain a very limited concentration of carbon tetrachloride (e.g., <0.003%) and EPA will further evaluate whether this is because the carbon tetrachloride is only present as an impurity. Relying on the 2010 IRIS assessment as a basis for consideration of health effects and dose-response information is appropriate and reasonable.

EPA Response:

Comment #3: HHS suggested that EPA should also consider NIOSH Health Hazard Evaluations for information on occupational exposures. A preliminary search pulled up 20 HHEs that may potentially have occupational exposure information on carbon tetrachloride (although only 2 were from 1990 or later).

EPA Response:

Dioxanes

Comment #1: Appendix A-1; P. 53., DOE asked that the following be inserted at the end of the table:

Department of Energy	The Atomic Energy Act authorizes DOE to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for Dioxane is 20 ppm (8 hr Time Weighted Average).

EPA Response: OK.

Comment #2: HHS noted that in 2015, EPA published a Problem Formulation and Initial Assessment for 1,4-Dioxane, from which much of the scoping document was taken. EPA has relied on the 2013 IRIS assessment for initial health effects and exposure-response information, which is reasonable and appropriate.

EPA Response:

Comment #3: HHS indicated that a search of the Health Hazard Evaluation database turned up 10 HHEs with potential information about occupational exposures to dioxane.

EPA Response:

HBCD - Cyclic Aliphatic Bromides Cluster

Comment #1: EPA

EPA Response: EPA

Comment #2: HHS noted that this scoping document included information for the flame retardants, hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane, and also 1,2,5,6-tetrabromocyclooctane, for which no uses have been identified. A Problem Formulation and Initial Assessment for the Cyclic Aliphatic Bromides Cluster was published by EPA in 2015, but a draft risk assessment was not completed. The major (>95%) use of HBCD is in extruded polystyrene foam and expanded polystyrene foam insulation products used in construction, but its use has been declining and is being phased out.

EPA Response:

Comment #3: Page 33, section 2.3.5.1, 1st sentence (typo). HHS suggested that "Section 0" should be "Section 2.2" (I think).

EPA Response:

Comment #4: Page 35, section 2.3.5.3, Inhalation, end of 1st paragraph (typo). HHS suggested that "Section 0" should be "Section 2.2" (I think).

EPA Response:

Comment #5: HHS noted that there is no IRIS Assessment, but EPA has previously compiled and reviewed the health effects as part of an effort toward drafting an IRIS Assessment, so that information was heavily relied on in this document. Because the materials were of a preliminary nature, EPA is planning to consider all hazard endpoints in the risk assessment.

Methylene Chloride

Comment #1: HHS noted that EPA completed its final TSCA risk assessment for methylene chloride in 2014, in which it considered a specific high volume use, paint and coating removers. Because the associated scenarios have already been assessed, an agency determination of unreasonable risk made, and restrictions on those uses proposed (in January 2017), these uses will not be re-evaluated in the risk assessment under this scope. Splitting the uses up among multiple risk assessments is not a procedure NIOSH has direct experience with. A question arises as to what happens if new information becomes available that substantially challenges the risk assessments (and perhaps the unreasonable risk findings) already completed. It would be helpful to include some information about what EPA would do in that eventuality – if not in this document, then in the problem formulation document.

With regard to potentially exposed or susceptible subpopulations, EPA might consider people with overt or silent heart disease as an especially susceptible subpopulation to the acute effects of methylene chloride because of its metabolism to carbon monoxide. This may be especially important for workers or consumers who would tend to be exposed to higher concentrations. [There are case studies in the literature of recovering heart patients being advised to do some occupational therapy and then ending up back in the emergency room after conducting their occupational therapy by refinishing furniture with methylene chloride and then being overexposed with pertinent sequelae.]

EPA Response: EPA

Comment #2: Page 16, table, Other U.S.-Based Organizations: should include OSHA assessment published in the Federal Register that supported its occupational exposure regulation. The reference is: 62 FR 1494-1619 (1997).

EPA Response: EPA

Comment #3: Page 37, 2nd paragraph, 1st sentence (typo): "Exposures routes" should be "Exposure routes"

EPA Response: EPA

Comment #4: Page 40, 2.4.2.1 Non-Cancer Hazards: HHS suggested that EPA should consider potential impacts on cardiovascular health because of methylene chloride's demonstrated metabolism (in humans) to carbon monoxide. Although the literature is not extensive on methylene chloride as a cardiovascular toxicant, the direct literature on the cardiovascular effects of carbon monoxide are fairly robust and could be used with methylene chloride pharmacokinetic information to assess risks.

EPA Response: EPA

Comment #5: Page 21, last paragraph, DOL/OSHA highlighted the following text: "For risk evaluations, EPA will assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory." Corresponding DOL/OSHA comments: *There are about 60 subcategories. Is EPA planning to make determinations for each subcategory or group them in response to what data is available? This section should be clarified.*

EPA Response: EPA

Comment #6: Page 25, 3rd row in table. DOL/OSHA noted that there might be a formatting issue. This makes this section look like it is in no category.

EPA Response: EPA

Comment #7: Page 34, 2.3.5.1. Occupational Exposures., first paragraph, last sentence. DOL/OSHA highlighted the following text: "When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels." Corresponding DOL/OSHA comments: *It might be important to consider that compliance rates for PPE are not 100%.*

EPA Response: EPA

Comment #8: Page 35, last paragraph on page. DOL/OSHA highlighted the following text: "Data that inform occupational exposure assessment and which EPA expects to consider as part of the occupational exposure assessment is the Occupational Safety and Health Administration (OSHA) Chemical Exposure Health Data (CEHD), which are monitoring data collected during OSHA inspections (OSHA, 2017). A preliminary summary of these data is presented in **Error! Reference source not found.**. These data represent actual exposure levels at methylene chloride specific workplaces encompassing several industry sectors and conditions of use. **Error! Reference source not found.** in **Error! Reference source not found.**summarizes OSHA CEHD data by all of the NAICS codes." Corresponding DOL/OSHA comments*: The data generated here is through a combination of complaints and "random" investigations. They may not be fully representative of actual concentrations. EPA should be aware that some sampling events were not taken over 8 hours. Many samples were taken less than an hour. However, the TWA values reported do not reflect this. While STELs are largely accurate, the TWA values often are not.*

EPA Response: EPA

Comment #9: Page 36, footnote a to the table. DOL/OSHA highlighted the following text: "Assumes all TWA data are 8-hour TWA." Corresponding DOL/OSHA comments: *As noted earlier, this assumption is inaccurate. Some of these reported TWA values are for samples of 15 minutes or less. Protocol requires the assumption that all unsampled time the concentration is 0 ppm.*

EPA Response: EPA

Comment #10: Page 49, 2.6.1.4. Occupational Exposures. DOL/OSHA highlighted text in the following sentence: "1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements)." Corresponding DOL/OSHA comments: *Is there a working criteria for what is reasonable?*

EPA Response: EPA

Comment #11: Page 49, 2.6.1.4. Occupational Exposures. DOL/OSHA highlighted text in the following sentence: "3) For conditions of use where data are not available, review existing exposure models that may be applicable in estimating exposure levels." Corresponding DOL/OSHA comments: *Will models be used in cases where there is minimal data?*

EPA Response: EPA

Comment #12: Page 51, 2.6.3. Risk Characterization. DOL/OSHA highlighted the section heading and made the following corresponding DOL/OSHA comments: *x-ref with PERC document: The description is somewhat vague on key details. For example, does EPA intend to use the same MOE approach as done in previous TSCA risk characterizations? How does EPA intend to characterize exposures? central and high-end point estimates or distributions? Does OPPT intend to use the slope factors,*

PBPK models or other risk-related information from the 2012 EPA IRIS document?

EPA Response: EPA

Comment #13: Page 72, Table_Apx B-1. DOL/OSHA highlighted the following text: "8-Hour TWA Exposure Concentration (ppm) [a]" and made the following comments: *As you noted, you assumed these were 8 hr TWAs based on 8 hr samples. Many of these samples are not. Some samples are extrapolations. OSHA is open to working with EPA to resolve these issues.*

EPA Response: EPA

Comment #14: Page 72, Table_Apx B-1, row for "321911," 5th column. DOL/OSHA highlighted the following text: "66" and made the following corresponding DOL/OSHA comments: *This value is actually below 10.*

EPA Response: EPA

Comment #15: Page 73, Table_Apx B-1, row for "321999," 5th column. DOL/OSHA highlighted the following text: "75" and made the following corresponding DOL/OSHA comments: *This value is around 50.*

EPA Response: EPA

Comment #16: Page 73, Table_Apx B-1, row for "325199," 5th column. DOL/OSHA highlighted the following text: "2,500" and made the following corresponding DOL/OSHA comments: *This sample and the 3200 value are approximations and not true measurements.*

EPA Response: EPA

Comment #17: Page 74, Table_Apx B-1, row for "325998," 4th column. DOL/OSHA highlighted the following text: "360" and made the following corresponding DOL/OSHA comments: *This value is incorrect.*

EPA Response: EPA

Comment #18: Page 74, Table_Apx B-1, row for "326199," 5th column. DOL/OSHA highlighted the following text: "890" and made the following corresponding DOL/OSHA comments: *This value is incorrect.*

EPA Response: EPA

Comment #19: Page 75, Table_Apx B-1, row for "332321," 4th & 5th column. DOL/OSHA highlighted the following text: "170" and "210." Then made the following corresponding DOL/OSHA comments: *Inaccurate.*

EPA Response: EPA

Comment #20: Page 79, Table_Apx B-1, Footnote a. DOL/OSHA highlighted the following text: "Assumes all TWA data are 8-hour TWA." Then made the following corresponding DOL/OSHA comments: *As noted earlier, this is an inaccurate assumption and many of the TWA values are incorrect.*

N-Methylpyrrolidone

Comment #1: HHS noted that EPA conducted a risk assessment of N-methylpyrrolidone (2015) and determined that risks to consumers and commercial users of NMP-containing paint removal products were unreasonable. EPA has proposed restrictions to address these risks. The same comment as above in methylene chloride and trichloroethylene applies here, with regard to how new information that may challenge existing risk assessment scenarios will be dealt with.

EPA Response: EPA

Comment #2: HHS noted that in the NIOSH HHE database, two HHEs were found that may contain information on occupational exposures to N-methylpyrrolidone.

EPA Response: EPA

Comment #3: Page 33, section 2.3.5.1, 2nd paragraph, last sentence (typo): HHS asked that EPA remove "which" from the sentence, "Risks associated with NMP use in paint removal which will not be re-evaluated."

EPA Response: EPA

Comment #4: Page 33, section 2.3.5.1, intro to bulleted list (typo): HHS noted that there is a missing "that" or "which" between "occupational exposures" and "will be considered"

EPA Response: EPA

Comment #5: Page 33, section 2.3.5.1, bulleted list: HHS commented that, in the previous paragraph you state that NMP use in paint removal will not be re-evaluated, but in your bulleted list of uses resulting in occupational exposures will be considered during the risk evaluation:, you include, "Applying NMP containing product formulations to substrates (e.g., applying paint removers containing NMP onto painted substrates) – shouldn't that use not be considered in this assessment, since you considered it in the previous risk assessment?

EPA Response: EPA

Pigment Violet 29

Comment #1: HHS noted that EPA conducted an initial literature search on this chemical to begin scoping. There is information on non-cancer endpoints in ECHA that EPA considered in drafting the scoping document, however, the information seems to be summary information only which will make it difficult for EPA to assess the hazards of this chemical. Although EPA has identified human health hazards of concern such as acute toxicity, irritation, sensitization and reproductive/developmental toxicity, it is not clear from this scoping document whether there are sufficient data to support a risk evaluation.

EPA Response:

PERC - Perchloroethylene (Ethene, 1,1,2,2-tetrachloro)

Comment #1: Appendix A-1; P. 54., DOE asked that the following be inserted at the end of the table:

Department of Energy	The Atomic Energy Act authorizes DOE to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for perchloroethylene is 25 ppm (8hr Time Weighted Average) and 100 ppm Short Term Exposure Limit(STEL).

EPA Response: OK.

Comment #2:

EPA Response: EPA

Comment #2: HHS indicated that although EPA has conducted an IRIS assessment of perchloroethylene (2012), this scoping document represents its first consideration under the new TSCA. The scoping document is lacking in details (which we presume are to come in the Problem Formulation document), but it appears EPA has done a reasonably good job of identifying potential occupational exposures. Relying on the 2012 IRIS assessment for the critical health effects and exposure-response information (with, of course, updates for new information) is reasonable and appropriate.

EPA Response:

Comment #3: With regard to occupational exposures, HHS suggested that EPA should consider information in NIOSH Health Hazard Evaluations https://www.cdc.gov/niosh/hhe/ . A preliminary search indicated that there are currently 62 HHEs that have information about perchloroethylene exposures. In addition, EPA should contact the NIOSH Industry-wide Studies Branch to determine if epidemiological cohort studies are available (or could be updated reasonably soon) that contain perchloroethylene exposure data.

EPA Response:

Comment #4: Page 29, 3rd paragraph, 1st sentence (typo): HHS indicated that "productive volume" should be "production volume."

EPA Response:

Comment #5: Page 20, last paragraph on page. DOL/OSHA highlighted the following text: "For risk evaluations, EPA will assess each use subcategory by identifying all potential sources of release and human exposure associated with that subcategory." With corresponding DOL/OSHA comments: *This should be clarified. There are over 50 subcategory conditions of use in Table 2-3. Does EPA intend to evaluate and make 'unreasonable risk' determinations on each subcategory? EPA may want to group use subcategories that are similar in application before conducting the risk evaluation to make the assessment process more manageable.*

EPA Response:

Comment #6: Page 23, last paragraph right before the table. DOL/OSHA highlighted the following text in the second sentence: "Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories." Corresponding DOL/OSHA comments: *Some processing subcategories in table below are used as chemical reactants or intermediates in which perc is entirely consumed to form another product. If the process is performed in a closed system, EPA might consider excluding this condition of use for risk evaluation.*

EPA Response:

Comment #7: Page 23, Table 2-3, 3rd Column, Header is highlighted. Corresponding DOL/OSHA comments: *See previous comment. Does EPA intend to separately evaluate and determine 'unreasonable risk' for each and every subcategory or will similar subcategories be further grouped by use application?*

EPA Response:

Comment #8: Page 34, last paragraph on that page. DOL/OSHA highlighted text in the following paragraph: "Data that inform occupational exposure assessment and which EPA expects to consider as part of the occupational exposure assessment is the Occupational Safety and Health Administration (OSHA) Chemical Exposure Health Data (CEHD), which are monitoring data collected during OSHA inspections (OSHA, 2017; Table 2-7). These data represent actual exposure levels at perchloroethylene specific workplaces encompassing several industry sectors and conditions of use. Table_Apx B-2 in Appendix B summarizes OSHA CEHD data by all of the NAICS codes." Corresponding DOL/OSHA comments: *EPA should be aware that most of the sampling data from CEHD come from OSHA inspections that were generated as a result of complaints and, therefore, may not be representative of perc concentrations in work establishments under the particular NAICS codes.*

EPA Response:

Comment #9: Page 36, Table 2-7, footnote a. DOL/OSHA highlighted the following text: "Assumes all TWA data are 8-hr TWA." Corresponding DOL/OSHA comments: *EPA needs to be careful interpreting the OIS TWA data. OSHA has found inspection data tagged in the database as 8-hr TWA but personal air samples were only collected over a few hours. In this situation, the worker may not have been exposed to that air level for a full 8-hours.*

EPA Response:

Comment #10: Page 51, Section 2.6.3. Risk Characterization. DOL/OSHA highlighted the section heading and made the following corresponding DOL/OSHA comments: *The description is somewhat vague on key details. For example, does EPA intend to use the same MOE approach as done in previous TSCA risk characterizations? How does EPA intend to characterize exposures? central and high-end point estimates or distributions? Does OPPT intend to use the slope factors, PBPK models or other risk-related information from the 2012 EPA IRIS document?*

EPA Response:

Comment #11: Page

TCE – Trichloroethylene

Comment #1: Appendix A-1; P. 63., DOE asked that the following be inserted at the end of the table:

Department of Energy	The Atomic Energy Act authorizes DOE to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for TCE is 50 ppm.

EPA Response: OK.

Comment #2: HHS noted that EPA completed its final TSCA risk assessment for trichloroethylene in 2014, in which it considered specific uses, vapor and aerosol degreasing, spot cleaning in dry cleaning and arts and crafts uses. Because the associated scenarios have already been assessed, an agency determination of unreasonable risk made, and restrictions on those uses proposed (in December 2016), these uses will not be re-evaluated in the risk assessment under this scope. As in my comment above for methylene chloride, splitting the uses up among multiple risk assessments is not a procedure NIOSH has direct experience with. The question of what happens if new information becomes available that substantially challenges the risk assessments (and perhaps the unreasonable risk findings) already completed is important to consider. It would be helpful to include some information about what EPA would do in that eventuality – if not in this document, then in the problem formulation document.

EPA Response:

Comment #3: HHS suggested that EPA should also consider occupational exposure information collected by the NIOSH Health Hazard Evaluation program https://www.cdc.gov/niosh/hhe/ . A quick search indicates that 75 health hazard evaluations have some information on TCE exposure in various workplaces. In addition, NIOSH may have exposure information in its Industry-wide Studies Branch that conducts occupational epidemiology. It would be worth contacting them to determine if some unpublished data exists that may be useful.

EPA Response:

Comment #4: Page 35, Section 2.3.5.4, first bullet: HHS requested that EPA please change the wording from "occupational bystander" to your more up-to-date language, "occupational non-user".

EPA Response:

Comment #5: Page 33, Table 2-7. DOL/OSHA highlighted the footnote indicators in the heading of the last column, and made the following corresponding DOL/OSHA comment*: Do not see b and c in footnotes to table*.

EPA Response:

Comment #6: Page 47, Section 2.6.1.4. Occupational Exposures. DOL/OSHA highlighted the following text in this sentence: "1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements)." Corresponding DOL/OSHA

comment: *How will EPA obtain the exposure data? Will manufacturer's be requested to provide any exposure data? What does "reasonably" available mean?*

EPA Response:

Comment #7: Page 47, Section 2.6.1.4. Occupational Exposures. DOL/OSHA highlighted the following text: "2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to TCE." Corresponding DOL/OSHA comment: *Such as? Which surrogates?*

EPA Response:

Comment #8: Page 47, Section 2.6.1.4. Occupational Exposures. DOL/OSHA highlighted the following text: "3) For conditions of use where data are not available, review existing exposure models that may be applicable in estimating exposure levels." Corresponding DOL/OSHA comment: *Models could also be used for conditions of use with "limited" data or to enhance analysis for conditions of use with some data.*

EPA Response:

Comment #9: Page 47, Section 2.6.1.4. Occupational Exposures. DOL/OSHA highlighted the following text: "6) Evaluate the weight of the evidence of occupational exposure data." Corresponding DOL/OSHA comment: *Not clear what is meant here by weight of evidence (quality of data? number of measurements?)*

EPA Response:

Comment #10: Page 47, Section 2.6.1.4. Occupational Exposures. DOL/OSHA highlighted the following text: "7) Map or group each condition of use to occupational exposure assessment scenario(s)." Corresponding DOL/OSHA comment: *Is the objective to estimate average exposure levels associated with conditions of use, or exposure distributions? What about peaks, upper 95%?*

EPA Response:

Comment #11: Page
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